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10/549302
JC05 Rec'd PCT/PTO 15 SEP 2005

INFORMATION DISCLOSURE STATEMENT

This Information Disclosure Statement accompanies the new patent application submitted herewith of the following Inventors: Michael HAGAN;

For: MUTANT CHOLERA HOLOTOXIN AS AN ADJUVANT AND AN ANTIGEN CARRIER PROTEIN.

1. Preliminary Statements

In accordance with 37 CFR 1.97 and 1.98, Applicants submit herewith patents, publications, or other information of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR 1.56. This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) the information is material to the examination of this application; (iii) additional information material to the examination of this application does not exist; (iv) the information, protocols, results and the like reported by third parties are accurate or enabling; or (v) the information constitutes prior art to the subject invention.

2. ☐ Previously Cited Information

No copy of the patents, publications or other information cited on the attached form PTO-1449 is enclosed because it has been previously cited by or submitted to the Office in a prior application which is relied upon for an earlier filing date under 35 USC 120. Prior application is Application Number _____ filed on _____ of _____ for _____.

CERTIFICATE OF MAILING 37 CFR §1.10

I hereby certify that this paper and the documents referred to as enclosed therein are being deposited with the United States Postal Service on the date written below in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EV100496605US addressed to the Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

September 15, 2005
Date

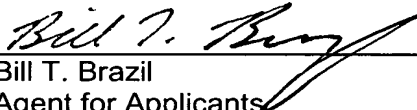
Karolina Piorek
Karolina Piorek

Docket No: AM100485

Patent

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3. ☒ Newly Cited Information
A legible copy of the patents, publications or other information cited on the attached form PTO-1449 is enclosed, except that no copy of a pending U.S. application, a U.S. patent, or a U.S. patent application publication is enclosed.
4. ☐ Concise Explanation
Documents cited above which are not in the English Language
- a. ☐ have been explained in the specification.
 - b. ☐ have an abstract (or other concise explanation) in English enclosed or, if readily available, a translation into English of the document is enclosed.
5. Form PTO-1449 is enclosed in duplicate.
6. Customer Number 25291.



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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known		
				Application Number		
				Filing Date		
				First Named Inventor		
				Group Art Unit		
				Michael HAGEN		
				Examiner Name		
				Attorney Docket Number		
				AM100485		
Sheet	1	of	1			

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number (If known)	Kind Code (If Known)			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Office	Number	Kind Code (If Known)				
	1.	WO	98/42375	A1	Chiron Corporation	10-01-1998		<input type="checkbox"/>
	2.	WO	97/02348	A1	Biocine S.P.A.	01-23-1997		<input type="checkbox"/>
	3.	WO	93/13202	A1	Sclavo Biocine S.P.A.	07-08-1993		
	4.	WO	00/18434	A1	American Cyanamid Co.	04-0602000		
	5.	WO	93/07178	A1	Pateur Merieux Serums	04-15-1993		
	6.	WO	01/74383	A1	UAB Reasearch Foundation	10-11-2001		
	7.	WO	02/47727	A1	UNIV. BRISTOL (GB)	06-20-2002		

OTHER PRIOR ART — NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.		T
	8.	HAJISHENGALLIS, G. et al., "Mucosal Immunization With a Bacterial Protein Antigen Genetically Coupled to Cholera Toxin A2/B Subunits," Journal of Immunology, 1995, 154(9): 4322-4332.	<input type="checkbox"/>
	9.	MARTIN, M. et al., "Recombinant Antigen-enterotoxin A2/B Chimeric Mucosal Immunogens Differentially Enhance Antibody Responses and B7-dependent Costimulation of CD4+ T Cells," Infection and Immunity, 2001, 69(1): 252-261.	<input type="checkbox"/>
	10.	JOBLING, Michael, et al., "Fusion Proteins Containing the A2 Domain of Cholera Toxin Assemble with B Polypeptides of Cholera Toxin to Form Immunoreactice and Functional Holotoxin-like Chimeras," Infection and Immunity, 1992, 60(11): 4915-4924.	<input type="checkbox"/>
	11.	GIANELLI, V. et al., "Protease Susceptibility and Toxicity of Heat-Labile Enterotoxins with a Mutation in the Active Site or in the Protease-sensitive Loop," Infection and Immunity, 1997, 65(1): 331-334.	<input type="checkbox"/>
	12.	SCHNEERSON, R., et al., "Synthesis of a Conjugate Vaccine Composed of Pneumococcus Type 14 Capsular Polysaccharide Bound to Pertussis Toxin," Infection and Immunity, 1992, 60(9): 3528-3532.	<input type="checkbox"/>
	13.	CARBONETTI, Nicholas H. et al., "Stimulation of HIV gp120-specific Cytolytic T Lymphocyte Responses In Vitro and In Vivo Using a Detoxified Pertussis Toxin Vector," Aids Research and Human Retroviruses, 2001, 17(9): 819-827.	<input type="checkbox"/>

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.